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From: Kimberly Prchal [Kimberly.Prchal@mdsps.com]
Sent: Friday, September 26, 2003 1:04 PM
To: adevor@clinimetrics.com
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Sensitivity: Confidential



Clinimetrics
Monitoring Prior...

Aimee,

Sorry for the delay, but I have finally come up with timelines for the monitoring of the Philip Morris studies. I have attached a spreadsheet for all of the studies.

The short term Marlboro study (MARL/02/03) will have first priority. For this study, LNK completed a group in Aug 2003 (Group 1 - 34 subjects randomized). Monitoring can begin anytime. The next group will also run in LNK starting 02 Oct and ending 13 Oct. We hope to have approximately 100 randomize (Group 2). Data should be ready to monitor by 20 Oct 03. The final group (Group 3P) will run in PHX starting 20 Oct and ending 31 Oct. We hope to have the remaining subjects randomize, approximately 100, to get the protocol required 225 subjects randomized. Data should be ready to monitor by 10 Nov 03. The timelines for this studies' monitoring are a bit tight so please let me know if you have any problems with staffing them.

The short term Series K (EHCK6/01/03) will have second priority. Susanna stated that 1/4 of data has previously been reviewed (screening packets, ICFs, drug accountability and about 20 CRFs). Susanna also mentioned that she will not be finishing this study to completion?

The long term JLI (EHCJLI/02/02) will have third priority. Our Lincoln CRF associate mentioned that Kathy Lawry reviewed about 1/2 of the Group 1 data and up to 3 month data for Group 1L1. Our Phoenix associates stated that Bob and Philip have reviewed all of Group 2P data and that 2P1 data should be reviewed by the end of this week. Another visit, or two, would be needed to clear up the queries and close out.

The long term Marlboro study (MARL/02/03) will have fourth priority. Since this is a continuation of the short term (MARL/01/03) it will also have 2 groups in Lincoln (Group 1 and 2) and one in Phoenix (Group 3P). We had 29 subjects agree to continue from Group 1 and the subjects are just about to return for their Week 6 visit (total of 24 Weeks). We have lost a couple and are now down to 24 subjects for Group 1. We will not know numbers of subjects for the long term Group 2 or 3P until about midway into the short term Groups 2 and 3P. We would like to have the entire 225 randomized subjects from the short term continue onto the long term. I have guesstimated timelines based on MDS internal dates.

I will be overseeing the coordination of monitoring for all Philip Morris studies, but the monitors should contact the study manager at each site to set up specific dates for visits.

I was sad to hear that Kathy Lawry has resigned. She was wonderful to work with and will be missed. Do you think that Philip will finish out the long term JLI study in LNK?

Please review the attached spreadsheet and let me know if you have any concerns.

Thanks
Kim

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